- NONCONFIDENTIAL -

2014-1391

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PAR PHARMACEUTICAL, INC.,
ALKERMES PHARMA IRELAND LIMITED,

Plaintiffs-Appellants,

v.

TWI PHARMACEUTICALS, INC.,

Defendant-Appellee.

Appeals from the United States District Court for the District of Maryland in Case No. 1:11-cv-02466-CCB, Judge Catherine C. Blake

APPELLANTS' NONCONFIDENTIAL BRIEF IN RESPONSE TO DEFENDANT-APPELLEE TWI PHARMACEUTICALS, INC.'S MOTION TO DISSOLVE INJUNCTION PENDING APPEAL

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CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Par Pharmaceutical, Inc. certifies the following:

1. The full name of every party or amicus curiae represented by me is:

   Par Pharmaceutical, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   Par Pharmaceutical, Inc., a nongovernmental corporate entity, is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. Par Pharmaceutical Companies, Inc. is a wholly-owned subsidiary of Sky Growth Holdings Corporation, which has no parent corporation, and no publicly held company owns 10% or more of the stock of Sky Growth Holdings Corporation.

4. The names of all law firms and the partners or associates that appeared for the party or amicus curiae now represented by me in the trial court or agency or are expected to appear in this court are:

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1. The full name of the party represented by us is: Alkermes Pharma Ireland Limited.

2. The name of the real party in interest represented by us is: not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are: Alkermes Pharma Ireland Limited is a subsidiary of Alkermes plc, a publicly held corporation. FMR LLC; Wellington Management Company, LLP; and T. Rowe Price Associates, Inc. all own 10 percent or more of Alkermes plc's stock.

4. The names of all law firms and the partners or associates that appeared for the party represented by us in the trial court or are expected to appear in this Court are:

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INTRODUCTION

The district court entered an injunction preserving the *status quo* for the remainder of this appeal, which is now fully briefed. This Court should decline TWi's invitation to second guess the court's discretion. Since January 2014, TWi has made repeated assertions that it would receive "imminent" FDA approval. The FDA still has not approved the accused product and TWi has not launched it. Yet the heart of TWi's challenge is that the district court should have found the timing of Par's Fed. R. Civ. P. 62(c) motion was unreasonable. The district court, which was uniquely positioned to understand the parties' actions and the timing of the docket below, addressed this argument and rejected it based on its management of its own proceedings.

Reaching even further, TWi also argues that the district court's finding that Par has presented a "substantial case" on appeal—which this Court and the Supreme Court have held to be the appropriate standard in a Rule 62(c) context—was somehow legal error. TWi's proposed standard is contrary to precedent. Further, Par's underlying appeal briefing outlines errors of law and clearly erroneous findings of fact in the district court's obviousness determination. These errors establish both a substantial case and a strong likelihood of success on the merits of the underlying appeal.

TWi finally asks this Court to further question the district court's discretion by finding that, based on a record containing expert declarations and supporting documents, the irreparable harm to Par is merely speculative and compensable. That also fails because the district court's finding of irreparable, concrete harm was anchored in the record.

This Court should deny TWi's motion to dissolve the injunction.

ARGUMENT

I. PAR FILED ITS RULE 62(C) MOTION AT A REASONABLE TIME

Before the district court, TWi opposed Par's Rule 62(c) motion based on laches. MA4.[1] The district court vetted the timing of Par's motion and TWi's allegations of prejudice, and found that "TWi has failed to demonstrate that it was sufficiently prejudiced by an unjustified delay." *Id.*

Before this Court, TWi (at 8-9) no longer asserts laches and does not argue prejudice. Instead, TWi asks this Court to revisit the district court's management of the timing of its own docket. TWi further asks (at 9) this Court to impose a

[1] "MA" refers to the Appendix to TWi's Motion to Dissolve Injunction Pending Appeal filed August 19, 2014. "A" refers to the Joint Appendix filed by Appellants on August 21, 2014.

new, rigid rule of law that prohibits Rule 62(c) motions unless they are filed by an unspecified date "early in the appeal."

The district court did not abuse its discretion in finding that Par filed its motion within a reasonable time. Further, this Court should decline to impose a new rule of law that constrains the equitable considerations underlying Rule 62(c). Such a rule would be contrary to controlling Supreme Court and Federal Circuit precedent holding that Rule 62(c) determinations "cannot be reduced to a set of rigid rules." *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 777 (1987)).

A. The District Court Correctly Determined That the Timing of Par's Rule 62(c) Motion Was Reasonable

TWi's asks (at 8-9) this Court to dissolve the injunction based on second guessing the district court's finding that Par filed its motion within a reasonable time. The record does not support TWi's position.

As an initial matter, there is no dispute that when Par had *credible* information that TWi's launch of the accused product was imminent, Par immediately sought to prevent that launch. The chronology demonstrates Par's reasonableness. **[**

CONFIDENTIAL MATERIAL OMITTED

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On February 21, 2014, the district court issued its ruling that the asserted claims of U.S. Patent No. 7,101,576 ("'576 patent") would have been obvious. Par filed its Notice of Appeal on March 18, 2014, and the underlying appeal is now fully briefed before this Court.

TWi asserts (at 5) that, following the district court's decision, "Par recognized that TWi was free to launch its product." That is incorrect. TWi relies (at 5-6) on three documents in which Par merely explained that TWi could theoretically launch *if* the FDA approved its ANDA. In fact, TWi had not received FDA approval and could not commercially market its product.

After failing to obtain regulatory approval it predicted in its January 14 correspondence, TWi never confirmed or denied its potential intent to **[**

] And Par's March 2014 10-K SEC filing merely stated that TWi had "disclosed its intent to launch . . . *should it receive* final FDA approval"—a condition that was not met at the time. MA318 (emphasis added). Similarly, Par's May 2014 10-Q filing addressed *projections* about sales of Megace® ES only at the unknown time "*when* generic competition enters the market." MA534 (emphasis added).

[

] TWi did not receive approval at the time of the district court's decision. Par thus reasonably understood that TWi faced a new review cycle before FDA approval could be forthcoming. MA505 ¶ 4. In the meantime, Par carefully monitored all publicly available sources for credible evidence of TWi's approval and launch. *Id.* ¶ 5.

TWi omits that, shortly after Par received updated, credible information regarding TWi's intended launch, it filed its Rule 62(c) motion. In early July 2014, Par learned of TWi's renewed expectation of FDA approval and plans to launch its generic product. *Id.* Specifically, Par obtained a Taiwanese analyst report ("KGI report") that revealed that TWi "expects it will receive final [FDA] approval **before August 2014**," and that the launch of the accused product was expected to occur "in 3Q14." MA65 (emphasis added).

Par immediately asked TWi about the "reports that TWi may plan to launch its product before the Federal Circuit decides the appeal," and added that such a launch "would cause serious irreparable harm." MA83. TWi responded on the same day, **[**

]

Par once again asked TWi whether it would agree not to launch until the resolution of the appeal pending before this Court. *Id.* Par explained that, absent such an agreement, it would be required to move for relief under Rule 62(c) and Federal Circuit Rule 8(a). *Id.* As of July 18, 2014, TWi had still not responded to Par's proposal. Par concluded that the information in the KGI report appeared to be credible in part because it contained financial projections based on the purported launch, and TWi is a public company in Taiwan. Based on that information, Par filed its Rule 62(c) motion before the district court.

Par's efforts contradict TWi's allegation (at 1) that "Par did nothing to extend an agreed preliminary injunction entered to allow the district court time to complete its opinion following trial, expedite the appeal, or even advise TWi that it would ever seek an injunction pending appeal." Moreover, to this day, TWi has not obtained FDA approval. MA10. The fact that Par's motion was filed and

granted weeks prior to the anticipated FDA approval of TWi's generic product underscores its timeliness. In its sound discretion, the district court found that Par filed its Rule 62(c) motion within a reasonable time. This Court should not disturb that finding.

B. TWi Asks This Court to Establish An Unfounded Absolute Rule Regarding The Timing of Rule 62(c) Motions

TWi asks (at 9) this Court to establish **a new rule of law** that would bar an appellant from filing a motion under Rule 62(c) "unless it does so early in the appeal." Such a rule would contradict the purpose of Rule 62(c) and the precedent of this Court and the Supreme Court.

TWi points to no language in Rule 62(c) that commands a rigid cut-off and it cites no legal authority to impose such a rule. That is unsurprising because Rule 62(c) determinations are equitable and inherently fact-specific. Indeed, this Court has recognized that, "the Supreme Court acknowledged, 'the traditional stay factors contemplate individualized judgments in each case, the formula cannot be reduced to a set of rigid rules.'" *Standard Havens*, 897 F.2d at 513 (quoting *Hilton*, 481 U.S. at 777).

In contrast to *Hilton* and *Standard Havens*, TWi seeks "a set of rigid rules" based only on four examples in which it contends that this Court—as a purportedly "routine" matter—expedited the appeal proceedings based on the timing of the Rule 62(c) motion before the district court. But just as the district court was free in

each of those cases to assess the timing of the motions at issue, so should the district court have discretion here.[2]

Nor is TWi's assertion (at 9) persuasive that "Par denied the Court and TWi the opportunity to expedite the appeal." In fact, TWi delayed the appeal by obtaining an extension to the briefing schedule over Par's objection. *See* ECF Nos. 52, 54, 55. In any event, the district court vetted any alleged harms to TWi, and TWi does not challenge its underlying findings. First, TWi does not have approval to market its product in any event. MA10. Second, TWi failed to provide any evidence of investments it made in the interim. MA4. Third, an injunction pending appeal simply shifts TWi's revenue to a future time period. MA10. Fourth, the bond will fully protect TWi from any losses during the appeal. MA12.

II. THE DISTRICT COURT PROPERLY APPLIED THE "SUBSTANTIAL CASE" STANDARD

TWi does not dispute the district court's determination that Par "made a showing of a substantial case" of likelihood of success on appeal. MA6. The district court's finding is thus dispositive. The Supreme Court has squarely held that under Rule 62(c), even in the absence of a "strong likelihood of success on

[2] A rigid rule requiring all Rule 62(c) motions to be filed by a certain deadline would encourage premature and unnecessary motion practice before the district courts.

appeal," the likelihood of success pending appeal may be established based on "a substantial case on the merits." *Hilton*, 481 U.S. at 778.

A. Controlling Precedent Supports The "Substantial Case" Standard

TWi incorrectly asserts (at 10-14) that the district court applied the wrong standard for evaluating an injunction pending appeal. The district court applied binding Supreme Court precedent. MA3 (citing *Hilton*, 481 U.S. at 776). TWi provides no plausible reason for this Court to act differently.

Rule 62 authorizes a district court that has entered final judgment to stay its judgment or grant an injunction "[w]hile an appeal is pending." Fed. R. Civ. 62(c)–(e). To determine whether such an order is appropriate, the Supreme Court has explained that the lower court must consider: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton*, 481 U.S. at 776.

While each factor should be considered, the test "contemplate[s] individualized judgments in each case." *Id.* "[T]he formula cannot be reduced to a set of rigid rules." *Id.*; *see also* 16A Charles Alan Wright et al., *Federal Practice & Procedure* § 3954 (2008) ("The four factors should be balanced; thus, for example, if the balance of harms tips heavily enough in the stay applicant's favor

then the showing of likelihood of success need not be as strong, and vice versa."). In granting Par's motion, the district court applied this standard, *see* MA3, considered each factor, *see* MA5-12, and balanced them appropriately, MA12.

TWi acknowledges (at 10) that *Hilton*'s rule controls. It does not contend that the district court failed to consider each factor. Rather, TWi contends (at 10) only that the district court erred in its evaluation of whether Par "'made a strong showing that [it] is likely to succeed on the merits'" of its appeal. *Id.* (quoting *Hilton*, 481 U.S. at 776).

According to TWi (at 10), *Hilton*'s first factor cannot be satisfied unless the movant demonstrates a "strong likelihood of success on the merits." TWi argues that the district court therefore erred by granting Par's motion based on its view that Par had "made a showing of a substantial case." MA6. That is incorrect.

In language that the district court quoted, *Hilton* explains that on a Rule 62 motion, the likelihood-of-success factor is satisfied "[w]here [a party] establishes that it has a strong likelihood of success on appeal, ***or where, failing that, it can nonetheless demonstrate a substantial case on the merits.***" 481 U.S. at 778 (emphasis added); *see also Standard Havens*, 897 F.2d at 513. TWi entirely ignores that portion of *Hilton*—yet it is dispositive of TWi's claim of legal error.

B. TWi's Arguments About Fourth Circuit Law Are Inapposite

In light of the district court's proper application of *Hilton*, the remainder of TWi's arguments on Par's likelihood of success fail. TWi criticizes (at 10-11) the district court for not clearly choosing whether Federal Circuit or Fourth Circuit law controls this Court's evaluation of Par's likelihood of success on appeal.

As an initial matter, while Fourth Circuit law may govern the overall Rule 62 framework, Federal Circuit law controls this Court's analysis of the likelihood of success in a patent appeal. *See Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 525-26 & n.1 (Fed. Cir. 2012) (rejecting the Second Circuit's "heightened standard" for likelihood of success for certain injunctions when applied to a patent case). This Court has expressly adopted *Hilton*'s "substantial case" standard. *Standard Haven*s, 897 F.2d at 513. In any event, Supreme Court precedent binds both circuits, and *Hilton* holds that the standard for likelihood of success under Rule 62 includes a substantial case on the merits.

TWi also asserts that the district court's analysis was contrary to *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008), because that case held that a movant for a preliminary injunction must "show both 'likelihood of success' and 'irreparable harm.'" Mot. 11-12 (citation omitted). That has no bearing on this case because the district court individually evaluated **each** of

Hilton's equitable factors, *see* MA5-6, and found that Par *did* satisfy both the likelihood-of-success factor and irreparable-harm factor, as defined by *Hilton*.

Winter does not call into question *Hilton*'s standard for likelihood of success in the context of a Rule 62 motion. *Winter* was primarily concerned with the irreparable-harm and public-interest equitable factors. It did not purport to define the showing required under the likelihood-of-success factor. *See Winter*, 555 U.S. at 23-24 ("[W]e do not address the lower courts' holding that plaintiffs have also established a likelihood of success on the merits."). It did not even cite *Hilton*. And it did not concern a motion for a stay or injunction pending appeal.

Contrary to TWi's contention, the fact that the standards for a preliminary injunction and injunction pending appeal "evolved from the same 'fourfold equitable rule of thumb'" does not mean that they are, in fact, the same. Mot. at 13 (quotation omitted). Although "[t]he [Rule 62] analysis . . . somewhat resembles the test applied in the district court when evaluating a request for a preliminary injunction, … the differences in posture mean that the two tests are not identical." Wright et al., *supra* § 3954; *see also id.* n.28 ("Observations concerning the similarity between the two standards should be tempered by a recognition" of their

differences)).[3] For this reason, this Court has continued to apply the *Hilton* standard when evaluating the likelihood-of-success factor post-*Winter*.[4] The district court rightly did the same.

C. There Is No Dispute That Par Has Shown A Substantial Case On the Merits Of Its Appeal

TWi does not even attempt to argue that the district court abused its discretion in holding that Par showed a "substantial case on the merits." As Par's briefing in the underlying appeal demonstrates, the district court's obviousness

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[3] TWi is thus incorrect that the Fourth Circuit's decision in *Real Truth About Obama, Inc. v. Federal Election Commission*, 575 F.3d 342, 345-47 (4th Cir. 2009), *vacated on other grounds*, 559 U.S. 1089 (2010), *and reaffirmed in part*, 607 F.3d 355 (4th Cir. 2010), which abrogated the Fourth Circuit's "balance-of-hardship test" in the preliminary injunction context, "applies with equal force to injunctions under [Rule] 62." Mot. 12-14 & n.2. It does not, as a majority of the district courts in the Fourth Circuit have held. *See, e.g.*, *In re Carroll*, No. 09-01177-8-JRL, 2012 WL 6115709, at *2 (Bankr. E.D.N.C. Dec. 3, 2012); *MicroStrategy, Inc. v. Business Objects, S.A.*, 661 F. Supp. 2d 548, 558 (E.D. Va. 2009).

[4] *See Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 31, 2010) (per curiam) ("To obtain a stay or injunction, pending appeal, a movant must establish a strong likelihood of success on the merits, or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor." (citing *Hilton*, 481 U.S. at 778)); *see also, e.g.*, *Merial Ltd. v. Cipla Ltd.*, 426 F. App'x 915, 915 (Fed. Cir. 2011) (same); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 425 F. App'x 896, 896 (Fed. Cir. 2011) (same); *Fred Hutchinson Cancer Research Ctr. v. BioPet Vet Lab, Inc.*, 423 F. App'x 996, 997 (Fed. Cir. 2011) (same); *Essex Electro Eng'rs, Inc. v. United States*, 433 F. App'x 901, 901 (Fed. Cir. 2011) (same); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 407 F. App'x 452, 452 (Fed. Cir. 2011) (same); *Tivo, Inc. v. EchoStar Corp.*, No. 2009-1374, 2009 WL 1939175, at *1 (Fed. Cir. July 1, 2009) (same).

determination contained legal error and, independently, was premised on clearly erroneous factual findings.

The district court correctly determined that Par discovered a serious and unknown problem in prior art treatment of wasting in HIV/AIDS patients. A10-20; Par Br. 3, 24; Par Reply 1-2. For nearly a decade before Par's invention, the prior-art Megace® OS product was marketed to treat severe weight loss in HIV/AIDS patients, yet the art remained unaware that patients in a fasted state—*i.e.*, the target population—did not effectively absorb the drug, leading to a 629%-787% food effect. *Id.* Par's invention reduced this food effect to 8%-55% for the most preferred embodiments. The district court concluded that the limitations of the asserted claims are narrowly tailored to substantially eliminating this previously unknown food effect. *Id.*

By contrast, in concluding that the asserted claims would have been obvious, the district court ignored specific claim limitations. It relied on "alternative" motivations to address the purported problems of viscosity and interpatient variability. But, as Par's briefing on appeal demonstrates (Br. 42, 49-53; Reply 3-10, 20-24), these would not lead to the specific food-effect limitations in the claims, and the court made no fact finding otherwise. Instead, the court found a *general* motivation to combine broad classes of references with no references to

solving the previously-unknown food effect. That analysis demonstrated hindsight bias and was legally erroneous. Par Br. 28-52, Reply 21-25.

The district court compounded its legal error by incorrectly applying the doctrine of inherency to address the food effect limitations. The court did **not** find that any of the specific claim limitations would **necessarily** result from its broad combinations. Par Br. 35; Reply 11-17. Instead, the court relied on a legally erroneous standard in which a claim limitation need only **sometimes** be present in the prior art. *Id.* In granting Par's Rule 62(c) motion, the district court recognized that this Court would decide these dispositive legal issues *de novo*, and found that Par established a substantial case. MA5-6.

As further legal error, the court disregarded the record of dramatic and unexpected results that Par's invention had on a problem that was undisputedly unknown in the prior art. Par Br. 57-61; Par Reply 17-20. And beyond these legal errors, the district court made several clearly erroneous fact findings regarding motivations to combine, teaching away, and long-felt and unmet need. Par Br. 44-53, 57-65; Par Reply 20-31. Thus, even if this Court were to overrule its prior holding in *Standard Havens*, Par's arguments on appeal would satisfy the "strong likelihood of success" standard.

III. PAR ESTABLISHED A RECORD OF IRREPARABLE HARM

TWi's asks this Court to reevaluate an evidentiary record that the district court analyzed and argues that Par has not suffered irreparable harm. But TWi does not point to a single unsupported finding by the district court, nor does TWi cite any legal error in the district court's opinion. The district court's finding of irreparable harm should not be disturbed.

A. The District Court Properly Found That TWi's Entry To The Market Would Destroy Par's Branded Division

TWi argues (at 14) that "Par's asserted threat that it *will possibly* shut down its Strativa department . . . is the kind of speculative harm that cannot support a finding of irreparable harm as a matter of law." TWi offers no support for its assertion. Contrary to TWi's assertion, Par only needs not show that irreparable harm is likely, not that it is absolutely certain. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008) (approving the factors the district court considered including "whether irreparable harm is likely if the injunction is not granted"); *see also Small v. Avanti Health Sys., LLC*, 661 F.3d 1180, 1191 (9th Cir. 2011) (holding that the movant "need not prove that irreparable harm is certain or even nearly certain").

TWi instead relies (at 15-16) on *In re Fenofibrate Patent Litigation*, 972 F. Supp. 2d 655, 657 (S.D.N.Y. 2013), for the proposition that "courts are rightfully suspicious of statements made in connection with a motion for an injunction that

are much more dire than those made to the public markets." That is inapposite here—the district court was not "suspicious" of Par's statements of harm nor did it have any reason to be. Par presented the declarations of Dr. Walter Vandaele, an economist, and John Ameres, Vice President of Marketing and Business Analytics at Strativa, to demonstrate that it would be forced to shut down its branded division absent an injunction. MA266-67 ¶¶ 22-23; MA253 ¶¶ 16-17; MA506-07 ¶¶ 6-9. The district court agreed, MA5-9, and TWi merely asks this Court to reevaluate the evidence.

TWi also argues (at 16) that Par's "internal decisions regarding what to do in the face of a measurable pecuniary loss" is not irreparable. As the district court noted, however, "TWi points to no authority for the position that harm is not irreparable where it only destroys a division of a company instead of the entire entity." MA8. TWi's position is contrary to Federal Circuit law, because "the fact that an infringer's harm affects only a portion of a patentee's business says nothing about whether that harm can be rectified." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1152 (Fed. Cir. 2011). In *Bosch*, the Federal Circuit explained that "[n]o one could seriously contend, however, that the irreparability of any particular injury should turn on incidental details such as a patentee's corporate structure." *Id.* That Par would have been forced to shut down its branded division is an irreparable harm.

Moreover, contrary to TWi's assertion (at 14) that closing Strativa (Par's branded division) is a *choice*, Par presented evidence that it would be economically *required* to close. **[**

] Moreover, as TWi recognizes, Mr. Ameres stated that **[** **]** to keep the division open absent an injunction. MA253 ¶ 17; MA507 ¶ 9. The district court properly found this harm irreparable.

B. Par's Damages Are Not Solely Financial

TWi argues (at 16) that Par's "boilerplate arguments universally invoked by pharmaceutical companies . . . have been rejected." None of the cases TWi cites involved a finding of even one of the harms that the district court found Par will suffer in this case. Par provided substantial evidence of harm that was specific to it and the market for megestrol acetate products.

The district court additionally found that Par will suffer irreversible price erosion and revenue losses due to the complicated third-party payor system, and loss of goodwill among patients who had begun purchasing the lower-priced generics. MA9. TWi's cited cases do not concern the impact of third-party payors and the formulary status system, and—unlike here—they do not involve findings

that the patentee will suffer loss of goodwill or will be forced to shut down a division or business. Yet precisely such harms are irreparable. *See Celsis In Vitro v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (finding the district court did not err in finding irreparable harm based on "price erosion, damage to ongoing customer relationships, loss of customer goodwill . . . and loss of business opportunities"). In the context of the third-party payor system, price erosion and loss of market share are irreparable. *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006).

TWi's assertion that Par's estimate of damages means that the harm is not irreparable misstates the evidence. As Dr. Vandaele explained, **[**

]

TWi's argument also lack legal support. "[T]he simple fact that one could, if pressed, compute a money damages award does not always preclude a finding of irreparable harm." *Celsis In Vitro*, 664 F.3d at 930. Instead, this Court has recognized that "[c]ompetitors change the marketplace. Years after infringement

has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction." *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996); *see also Canon, Inc. v. GCC Int'l Ltd.*, 263 F. App'x 57, 62 (Fed. Cir. 2008) ("Due to the difficulty (if not impossibility) of determining the damages resulting from price erosion and loss of market share, an award of money damages would not be sufficient.").

Moreover, TWi asserts (at 18) that Par's "losses in this context are seldom seen as sufficient to support the issuance of any injunction." As an initial matter, TWi relies on district court cases that do not relate to the harms at issue in this case. The cited cases suggest that even if Par would not suffer the irreversible price erosion and loss of goodwill, Par would still be able to demonstrate irreparable injury because it would be forced to shut down its branded division. *See, e.g.*, *Mylan Labs., Inc. v. Leav*itt, 495 F. Supp. 2d 43, 48 n.7 (D.D.C. 2007) (recognizing that, despite the court's conclusion that the patentee only suffered compensable economic damages the harm could be irreparable if the patentee could show "dilution of its market share would likely lead to financial collapse").

CONCLUSION

For the foregoing reasons, this Court should deny TWi's Motion to Dissolve Injunction Pending Appeal.

Dated: August 25, 2014

Respectfully submitted,

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DECLARATION OF AUTHORITY PURSUANT TO FEDERAL CIRCUIT RULE 47.3

Pursuant to Rule 47.3(d) of the Rules of the United States Court of Appeals for the Federal Circuit, I, Daniel G. Brown, of Latham & Watkins LLP, hereby swear under penalty of perjury pursuant to 28 U.S.C. § 1746 that Maryellen Noreika, Counsel for Plaintiff-Appellant Alkermes Pharma Ireland Limited, has authorized me to sign the Appellants' Nonconfidential Brief In Response To Defendant-Appellee TWi Pharmaceuticals, Inc.'s Motion To Dissolve Injunction Pending Appeal on her behalf.

Executed on: August 25, 2014

/s/ Daniel G. Brown
Daniel G. Brown

CERTIFICATE OF SERVICE

I certify that on August 25, 2014, the foregoing APPELLANTS' NONCONFIDENTIAL BRIEF IN RESPONSE TO DEFENDANT-APPELLEE TWI PHARMACEUTICALS, INC.'S MOTION TO DISSOLVE INJUNCTION PENDING APPEAL was filed electronically using the CM/ECF system, which will send notification of such filing to counsel of record.

I further certify that I caused copies of the APPELLANTS' CONFIDENTIAL BRIEF IN RESPONSE TO DEFENDANT-APPELLEE TWI PHARMACEUTICALS, INC.'S MOTION TO DISSOLVE INJUNCTION PENDING APPEAL to be served via FedEx priority delivery upon the following:

Donald J. Mizerk
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/s/ Daniel G. Brown
Daniel G. Brown

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)

Counsel for Appellants, Par Pharmaceutical, Inc., and Alkermes Pharma Ireland Limited hereby certify that:

1. This Response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d): The Response does not exceed 20 pages, excluding the parts of the Response exempted by Federal Rule of Appellate Procedure 27(d) and Federal Circuit Rule 27(d).

2. This Response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d): The Response has been prepared in proportionally spaced typeface using Microsoft Word in 14 point Times New Roman style font.

Dated: August 25, 2014

Respectfully submitted,

/s/ Daniel G. Brown
Daniel G. Brown